RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)
COMPLIANCE EVALUATION INSPECTION REPORT

Boston Scientific (Guidant)

EPA ID Number: **PRD987370723**

Site Address
Mailing:
State Road 698, No. 12, Suite 1
Dorado, Puerto Rico 00646-3309

Physical:
State Road 698, No. 12, Suite 1, Dorado, Puerto Rico 00646-3309

NAD83 Puerto Rico Virgin States Plane
Latitude: 18°27'58.78"N
Longitude: 66°16'08.70"W

Attendees:
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Inspection Date: August 18, 2011

CEPD-RCRA-12-0225
Record Schedule: 478(b)

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1.0 INTRODUCTION

A Resource Conservation and Recovery Act (RCRA) compliance evaluation inspection (CEI) was conducted on August 18, 2011 at Boston Scientific (Guidant) located on State Road 698, No. 12, Suite 1, Dorado, Puerto Rico. The evaluation inspection consisted of an opening interview, a site tour, a review of facility documents, and a closing interview. Boston Scientific is designated in the RCRAInfo database as a Large Quantity Generator (LQG) facility. According to RCRAInfo database, Boston Scientific was last inspected (CEI) by the Puerto Rico Environmental Quality Board on March 18, 2010, and November 5, 2008, respectively. The facility was evaluated in the areas of general generator requirements, and no violations were found by EQB.

1.1. FACILITY OPERATION

Boston Scientific is an industrial facility engaged in the manufacturing of medical devices used in the treatment and surgical operations of cardiovascular diseases. The Facility began operations in 1990 in Dorado, Puerto Rico and employs approximately 550 full time employees rotating two shifts from Mondays to Fridays depending on the production demands. Boston Scientific is classified as a light manufacturing industry primarily engaged in the assembly of implantable medical products in a controlled environment. Process steps employed at the facility during the manufacturing process include: 1) laser welding, 2) testing, 3) molding, 4) packaging, and others. Products manufactured primarily include electrode leads, which are used in the treatment of cardiovascular diseases. Manufacturing events at Boston Scientific take place using physical processes only.

As part of its manufacturing activities, hazardous wastes are generated. The facility consists of manufacturing areas which comprised of one (1) large single story main building, and four (4) separate, freestanding smaller concrete structures, housing its Hazardous Waste Storage Area, the Emergency Power Generator Building, the Mechanical Building, and the Emergency Fire Pump Station. The plant size covers approximately 182,000 sq. in a 23.5 acres of land property in Dorado.

Boston Scientific specializes in the production of cardiovascular products. Among the main products portfolio manufactured, Boston Scientific's primary products include: i) Bradycardia – Flextend Lead, which is used to treat arrhythmias where the heart beasts too slow; ii) Heart Failure-Easytrak Lead "Acuity," which is used to treat congestive heart failure; and, iii) Tachycardia-Reliance, which is used to trea arrhythmias where the heart beats too fast. In order to support facility's manufacturing processes several chemicals are used in the manufacturing process, equipment cleaning, equipment lubrication and water treatment. Most of these materials are stored in a warehouse located on premises.

1.2. Solid and Hazardous Waste Generation

Typically, solid waste is generated from packaging medical devices residues, discarded raw materials, impacted rags with solvents, and office paper work. Their solid waste is disposed of in a municipal landfill or by LM Waste Services Corp.

Industrial and sanitary wastewater is treated on-site through an aqueous neutralization wastewater treatment plant, and it is discharged to the Puerto Rico Aqueducts and Sewer Authority-Regional Wastewater Treatment Plant. In general, the Facility used to generate contaminated rags (D001), laboratory packs (D001, D002, D003, D006, D008, F003, and acetonitrile-ACN), and expired raw material. Most of them were flammable spent solvents. All the hazardous waste are disposed of with Veolia Technical Solutions. Based on these waste quantities, the Facility used to be classified as a large quantity generator (LQG).

Other solid wastes generated at the facility were Universal Waste (UW-D009) associated with the management of spent fluorescent lamps, and disposal of unused sanitation, maintenance and housekeeping products.

1.3. Physical Setting

The site is located at approximately 28 feet above mean sea level. **Figure 1** presents the site location on a portion of the US Geological Service (USGS) Topographical Map. **Figure 2** presents an aerial photograph of the site. The closest superficial water body is the Atlantic Ocean located approximately 0.35 miles to the north of the site.

2.0 Opening Meeting

An opening meeting was held between Juan C. Kuang, VP & General Manager, Peter Rodriguez, Process Engineering Director, and Ariel Gonzalez, Environmental, Safety, and Health Manager, form Boston Scientific and me. I discussed the objectives of my inspection, and the requirements under RCRA for a Large Quantity Generator (LQG). I asked Mr. Ariel Gonzalez to provide me for review Boston Scientific's manifests (last three years), and land disposal records regarding the handling, transportation, and final disposal of hazardous waste generated, and stored at the facility. I also asked for review the waste analysis plan, weekly inspection schedule, personnel training requirements, biennial report, financial requirements, waste minimization plan, closure plan, contingency and emergency and preparedness plan, SPCC (Used Oil), and RCRA air emission requirements under Subparts AA, BB & CC inspection documents.

Mr. Gonzalez stated that Boston Scientific does not have to comply with Subparts AA, BB & CC of RCRA requirements, since the only area was the hazardous waste container storage area. He added that containers holding volatile organic waste are provided with a cover and manufactured tested in accordance with DOT requirements, and the United Nations (UN) Performance Oriented Packaging Standards (49 CFR 178). In addition, Boston Scientific's container

management practices (transferring, storing, and stacking) are provided to prevent and control of volatile air emissions.

From a review of the manifests, it was estimated that approximately over 2,200 pounds of hazardous waste. I was told by Mr. Gonzalez that there are one hazardous waste container storage area and various hazardous waste satellite areas for the management of hazardous waste in the areas of the manufacturing and assembling quality control areas.

3.0 SITE TOUR

As part of the compliance inspection, a walkthrough of the facility was conducted. At this point, Mr. Ariel Gonzalez accompanied me on a walk-through inspection of the facility.

3.1. CEA-A (NEW PRODUCTS) AREA

The first area I inspected was the CEA-A area where various assembling rooms in which different medical cardiovascular products are planned to be assembled. At the time of the inspection, I observed that the area was under renovation for new product lines, and seemed clean and empty.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

3.2. PRODUCTION TEAMS (ME/QE/IE) AREA

I proceeded to inspect the Production Teams (ME/QE/IE) area where various assembling lines area evaluated, and designed for different medical cardiovascular products. This area consists mostly of planning offices and assembling design by multimedia teams. There are no generation of hazardous waste at this area.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

3.3. CEA-B (NEW PRODUCTS) AREA

I proceeded to inspect the CEA-B area where various assembling rooms in which different medical cardiovascular products are assembled. At the time of the inspection, I observed that most manufacturing activities taking place were based on physical processes, and no generation of hazardous waste was observed.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

3.4. CEA-C (ALL PRODUCTION LINES) AREA

I proceeded to inspect the CEA-C (All Production Lines) area where various assembling rooms in which different medical cardiovascular products are assembled. At the time of the inspection, I observed that once implantable medical products were finished, there were sterilized with ethylene oxide.

At the CEA-C, I observed two satellite areas one containing one (1) 5-gallon container with rags impregnated with isopropyl alcohol, and the other containing one (1) 5-gallon drum with rags impregnated with Heptane. All containers were properly labeled and in good conditions.

Observations at this area rendered no concerns regarding the generation and management of hazardous wastes.

3.5. FINAL PACKAGING AREA

I proceeded to inspect the Final Packaging area in which final manufactured products are sterilized and properly packed and put in cardboard boxes for further shipments. At the time of the inspection, I observed two satellite areas one containing one (1) 5-gallon container with rags impregnated with isopropyl alcohol, and the other containing one (1) 5-gallon drum with rags impregnated with Heptane. All containers were properly labeled and in good conditions.

As stated by Mr. Gonzalez most of the packing area activities are dry processes that do not generate much hazardous waste.

3.6. RECEIVING/SHIPPING QC AREAS

I proceeded to inspect the Receiving/Shipping QC Areas in which new manufactured parts products are received and distributed for further plant processing or shipment. At the time of the inspection, I observed two satellite areas one containing one (1) 15-gallon container with rags impregnated with isopropyl alcohol, and the other containing one (1) 15-gallon drum with rags impregnated with Heptane. All containers were properly labeled and in good conditions.

As stated by Mr. Gonzalez most of the receiving area activities are parts products processes that do not generate much hazardous waste.

3.7. WAREHOUSE RAW MATERIAL "CRIB" AREA

I proceeded to inspect Warehouse Raw Material "Crib" area in which all raw materials, solvents, and equipment parts are received and organized in shelves. It was observed a strict inventory program in place that goes along with the manufacturing planning. Active ingredients and equipment parts are inspected and accounted for plant distribution.

Observations at this area rendered no concerns regarding the generation or management of hazardous wastes.

3.8. HAZARDOUS WASTE STORAGE AREA/90-DAY CENTRAL ACCUMULATION AREA (CAA)

I proceeded to inspect the Hazardous Waste Storage Area and the 90-day central accumulation area (CAA) in which all hazardous waste collected from all manufacturing process satellite areas are transferred and stored at this area. In addition, all hazardous waste generated from quality assurance and quality control tests, as well as laboratory packs area stored in this area before final disposition with Veolia Technical Solutions. The area is an enclosed warehouse with reinforced concrete floor. It has an estimated storage capacity of 50 55-gallon drums. As observed, the base floor was free of cracks or gaps, and it was designed to contain leaks and spills in a collection sump.

Inside the Hazardous Waste Storage Area and CAA, I observed the following;

- Ten (10) 55-gallon drums containing flammable solids (IPA/Heptane-D001), clearly labeled with the words, "Hazardous Waste," and dated on July 11, 2011, July 12, 2011, July 15, 2011, July 21, 2011, July 26, 2011, July 29, 2011, August 1, 2011, August 5, 2011, August 9, 2011, and August 12, 2011, respectively;
- Four (4) 55-gallon drums containing flammable solid organics (Xylene/Turpentine-D001,F003), clearly labeled with the words, "Hazardous Waste," and dated on July 22, 2011, July 22, 2011, July 22, 2011, and August 17, 2011, respectively;
- One (1) 55-gallon plastic drum containing Dimethyl-Methyl-Hydrogen, clearly labeled with the words, "Hazardous Waste," and dated on July 14, 2011;
- One (1) 55-gallon drum containing waste flammable liquid (Acetonitrile – D001), clearly labeled with the words, "Hazardous Waste," and dated on July 14, 2011;
- One (1) 55-gallon drum containing waste flammable liquid (IPA/Heptane/Alcide-D001), clearly labeled with the words, "Hazardous Waste," and dated on August 8, 2011;
- One (1) 55-gallon drum containing Environmental Hazardous Substances (Sodium Phosphate Monobasic – Blood Stimulator), clearly labeled with the words, "Hazardous Waste," and dated on July 14, 2011;
- One (1) 55-gallon drum containing waste flammable liquid (IPA/Sodium Phosphate-D001, D002), clearly labeled with the words, "Hazardous Waste," and dated on July 16, 2011;
- Eight (8) 55-gallon drums containing flammable solids (IPA/Heptane-D001), clearly labeled with the words, "Hazardous Waste," and dated on July 11, 2011, July 14, 2011, July 19, 2011, July 22, 2011, July 28, 2011, August 1, 2011, August 5, 2011, and August 11, 2011, respectively;
- One (1) 55-gallon drum containing white chiller cleaning corrosive residues-corrosive liquid inorganic acid (Hydrochloric Acid-D002), clearly labeled with the words, "Hazardous Waste," and dated on July 1, 2011;
- One (1) 30-gallon container with Hydrochloric Acid (D002) residuals, clearly labeled and dated on July 19, 2011;
- One (1) 5-gallon container with spent vials of acetonitrile waste (D001) clearly labeled and dated on July 19, 2011;

- One (1) 3-Liter container with spent N-N Dimethyl Hydrogen, clearly labeled and dated on August 17, 2011;
- One (1) 2-Liter container with waste arsenic (D006), clearly labeled and dated on July 21, 2011; and,
- One (1) 500-grams container with spent sodium lauryl-sulfate (D002), clearly labeled and dated on August 13, 2011.

As observed, all the drums and containers were clearly labeled with the words, "Hazardous Waste," and were dated with its accumulation start dates from the date of generation. Additionally, all the drums holding hazardous waste were in good conditions. No leaks were observed on the floor.

The hazardous wastes containers storage area at Boston Scientific was equipped with fire alarms, emergency system and security system.

According to Mr. Gonzalez, the spent fluorescent lamp bulbs are also collected and disposed of as hazardous waste (D009) with Veolia Technical Solutions.

3.9. Quality Assurance Laboratory Area

Mr. Gonzalez escorted me to finally inspect the Quality Assurance Laboratory where most of the quality assurance and quality control tests are performed on most campaign medical products. I observed four (4) High Performance Liquid Chromatography (HPLC) equipment running different tests continuously and generating waste in its satellite units. Most of the waste generated is acetonitrile and water (D001, F003) spent solvents. I observed tow (2) 10-gallon containers accumulating hazardous waste from HPLC equipment labeled with its waste content. There were two (2) 5-gallon additional containers accumulating hazardous waste from HPLC equipment clearly labeled (ACE-Waste). I also observed three (3) 5-gallon containers used to transfer acetonitrile, hydrochloric acid, and isopropyl alcohol spent solvents to the satellite areas. There were two (2) 5-gallon additional containers accumulating IPA/Heptaned, and N-N Dimethyl Formalin hazardous waste. All containers were filled with spent solvents, and were all clearly labeled.

Additionally, it was noted that the facility has available and visible at every location a list of names and telephones in case of an emergency as well as two-way radio. The facility also has alarm system, sprinkler systems, telephones and extinguishers.

After our walk-through inspection, we proceeded to review facility records. Mr. Jesus Santos accompanied me to the conference room to assist me during my document review.

4.0 Document Review

The following records were reviewed as required by the RCRA Permit during the inspection:

- Manifest Records and Land Disposal Restriction Forms (LDR) - Manifests and associated LDRs for all incoming and outgoing shipments for the three years were reviewed. It appeared to be properly maintained and in compliance.
- Personnel Training Records - The facility provided personnel training records, last provided by an outside contractor in June 2011. It appeared to be in compliance.
- Waste Analysis - A Full RCRA analysis was provided for the Toxic Characteristic Leaching Procedure (Test Method SW 1311) tests were performed as required by the Waste Analysis Plan. It appears to be in compliance.
- Weekly Log Records – All weekly logs records for daily and weekly tank and container storage areas were reviewed and found to be in compliance.
- Air Emissions Record – 40 CFR Part 264 Subpart AA, BB, and CC – All facility record related to the RCRA air emission requirements were requested. According to Mr. Gonzalez, Boston Scientific does not have to comply with Subparts AA, BB & CC of RCRA requirements.
- Contingency and Emergency Preparedness Plan - There was a Contingency and Emergency Preparedness Plan, dated October 2009 at the time of the inspection. In general, the plan provided a list of names and telephones in case of an emergency and proper procedures in a case of an emergency. As observed the Contingency Plan was ready accessible, and so the plan was also posted and accessible to all employees and provided to emergency agencies. (i.e., Fire Department, Hospitals, Police Department, and Civil Defense). Additionally, the Facility was equipped with alarm systems, sprinkler systems, telephones, certified extinguishers nearby areas were hazardous wastes were stored under the RCRA Permit.
- Biennial Report – All Biennial Reports were reviewed as required. It appeared to be properly maintained and in compliance.
- Waste Minimization – The Waste Minimization report and waste reduction data were evaluated. It appears to be in compliance.

5.0 CLOSING INTERVIEW

After completion of the walkthrough and document review, the EPA Inspector met with Juan C. Kuang, VP & General Manager, Peter Rodriguez, Process Engineering Director, and Ariel Gonzalez, Environmental, Safety, and Health Manager, to conduct a closing meeting. I indicated that the purpose of the closing meeting is to inform the Facility's representatives about the RCRA observations. I asked about some EPA's concerns before I can reach a full compliance determination of the RCRA program as follows:

EPA's Concern No. 1: Explain the rationale for current sequential process of hazardous waste storage and Satellite Accumulation Areas (SAAs) in the manufacturing lines.

Boston Scientific's (BSC) Response: BSC Dorado operates production lines where the operators work at benches; many benches will make up a production line. As part of the process, they use wipes with alcohol. After use these wipes are collected in small, covered blue bins at the individual bench work station where they are under the control of the operator of the process.

When the operator needs to leave his bench or at the end of his shift, the wipes are taken to an established SAA where they are consolidated into a red, 5-gallon SAA container. In general, each line has two SAAs; one is located at the start of the line and the other at the end of the assembly line. Each SAA container has a label in accordance with 40 CFR 5262.34(c)(1)(ii). The blue bins are considered collection points for in-process waste while the red cans are considered SAAs.

EPA guidance regarding this practice has a guidance document dated December 3, 2009 regarding closed containers does include the following statement:

> "it would be permissible if spent solvent was generated at the bench and then consolidated into a 55 gallon container at the end of the shift within the same SAA, so long as the waste remained 'at or near' the point of generation and under the control of the operator".

The process used for management of alcohol wipes on the BSC Dorado production lines is consistent with this EPA guidance, in that the wipes are generated at a bench, remain in the blue bins until placed into a SAA, and remain under the control of an operator throughout that time.

BSC also considers the use of the blue bins part of the production process or "in-process", and not as individual SAA containers. The practice of using these bins, and transferring their contents by operators which generated the wipes to a SAA during a shift or at the latest at shift end, is consistent with the available EPA guidance and further interpreted state guidance. On this basis, we believe that this is an appropriate and legally-compliant practice.

EPA's Concern No. 2: Provide justification for the wipe compaction as an exception in the hazardous waste Disposal Procedure.

Boston Scientific's (BSC) Response: BSC generates numerous waste IPA wipes. These wipes are compacted to minimize the number of drums that are shipped off-site for proper hazardous waste disposal. The compaction process takes place in our 90-day central accumulation area (CAA), in 55 gallons drums. The compaction process does not result in a change in physical, chemical, or biological character or composition of waste as defined in 40 CFR §260.10. Although this activity does reduce the number of drums BSC needs to ship off-site for disposal, it does not reduce the volume or nature of the wipes themselves. Instead, it reduces/eliminates the air space between the wipes within the drums. Therefore, BSC does not consider the compaction activity as "treatment". This understanding is also consistent with the interpretation made by the State of Connecticut Department of Environmental Protection.

In addition to the Connecticut DEP letter, the EPA has provided clarification in a letter, dated May 21, 1991 which states:

> "...a machine that compacts hazardous waste in a drum will meet the definition of treatment if the reduction in volume results in a change in the physical, chemical, or biological character or composition of the waste."

Although the compaction reduces overall volume required for waste storage, it does not change the physical, chemical or biological character or composition of the waste. Given this information, we do not believe that the on-site waste compaction activity meets the definition of "treatment", and that our current practices are compliant with the applicable regulations. Although we do not believe this practice constitutes treatment, we understand that EPA does allow a generator to treat their waste in accumulation containers or tanks without a permit. Generator treatment in containers is allowed as long as the requirements of Subpart I are met, the containers are dated and labeled properly, and are not stored for more than 90 days. BSC Dorado conducts its compaction activities in compliance with each of these requirements.

EPA's Concern No. 3: Document how current DOT-approved drums comply with air emissions requirements for closed drums, within RCRA standard.

Boston Scientific's (BSC) Response: BSC uses UN/ DOT approved 55-gallon containers for hazardous waste accumulation, complying with applicable requirements of 40 CFR Subpart CC. Specifically, 40 CFR 265.1087(b)(1)(i) states that for a container having a design capacity greater than 0.1 m3 (approximately 26 gallons) and less than or equal to 0.46 m3 (approximately 119 gallons), the owner or operator shall control air pollutant emissions from the container in accordance with the Container Level 1 standards. Container Level 1 controls require that the hazardous waste is stored in (1) an approved Department of Transportation (DOT) container, (2) a container equipped with a cover and closure devices for each opening, or (3) an open top container with an organic-vapor suppressing barrier, such as a tight fitting trap or an organic-vapor suppressing foam. BSC uses approved DOT containers and keeps containers closed. The drums are always properly covered with snap rings tightly closed, and bungholes are also tightly closed. Inspections to all drums in the CAA are performed on a weekly basis. The weekly inspections that include the inspection of drums and verify if they are properly closed, were reviewed during your visit. On this basis, we believe that the use of drums in this manner is a compliant practice.

EPA's Concern No. 4: Chemical compatibility; address with training and procedure requirements.

Boston Scientific's (BSC) Response: BSC conducts chemical compatibility reviews and training for affected personnel. As a result of your recent inspection, chemical use was reviewed and training materials were updated. A revised chemical hygiene plan and updated training records were provided. Additional training for laboratory personnel and hazardous waste handlers has been completed to assure incompatible materials are stored separately.

After responding to EPA's concerns, EPA determined that the hazardous waste management program at Boston Scientific Dorado (Guidant) was satisfactory as required by the RCRA program, and that no violations on applicable hazardous waste regulations were found. Therefore, I communicated to Juan C. Kuang, VP & General Manager, Peter Rodriguez, Process Engineering Director, and Ariel Gonzalez, Environmental, Safety, and Health Manager, that no further enforcement action would be required by EPA.

6.0 COMPLIANCE ASSISTANCE

The EPA inspector discussed with Boston Scientific's representatives the specific RCRA program regulations that apply to the Facility, and how to stay in compliance in case they decide to minimize or recover waste streams and implement waste minimization/pollution prevention procedures as required by RCRA.

7.0 POTENTIAL MULTI-MEDIA ISSUES

There is no referral to other programs.

8.0 ENFORCEMENT ACTIONS

Based on the observations made during the inspection, the following enforcement actions are recommended:

1. No enforcement action is warranted at this facility.

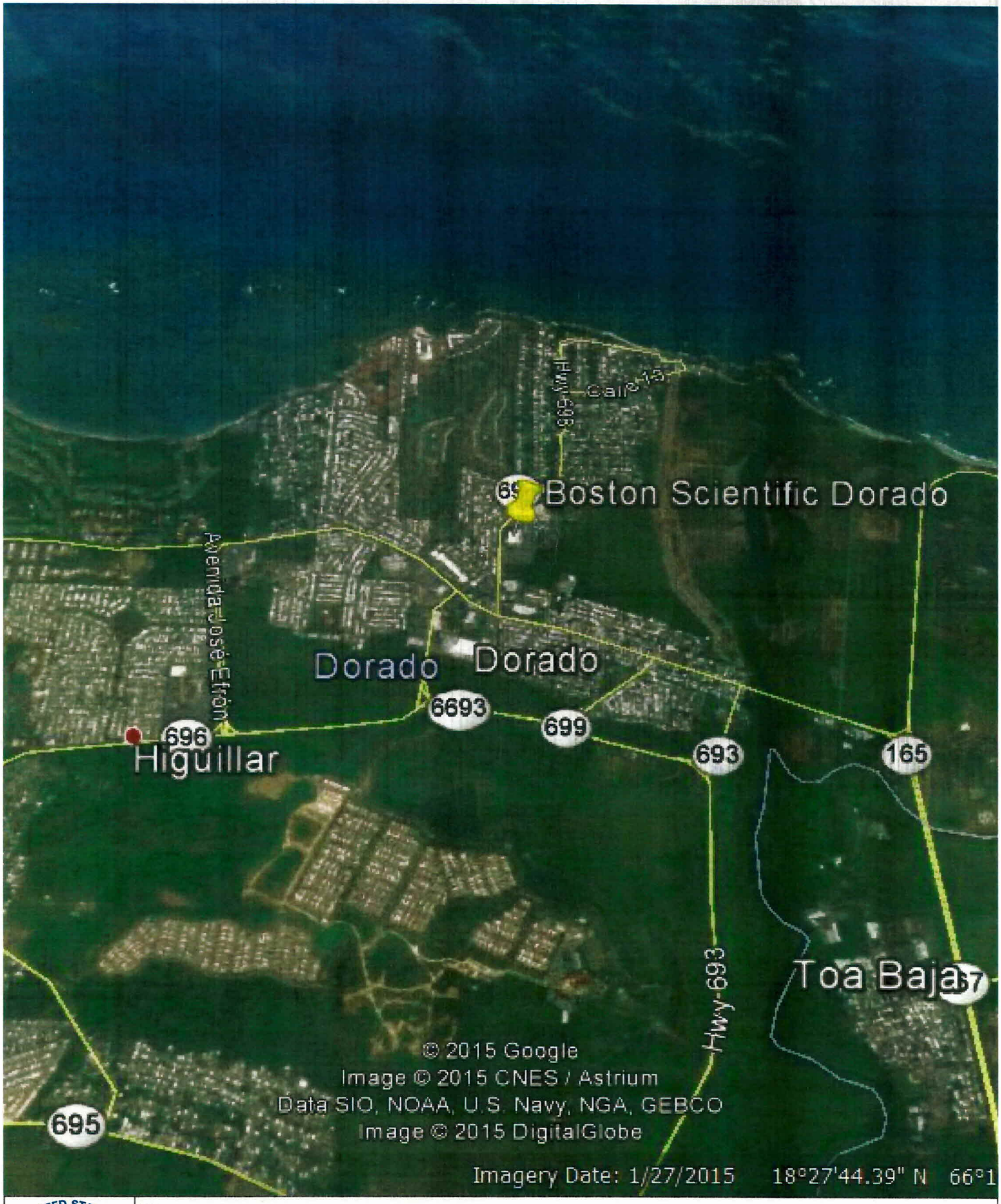
Eduardo Gonzalez — July 9, 2015

Eduardo Gonzalez, P.E., RCRA Inspector — Date

Ramon Torres — 7/13/15

Ramon Torres, RRB Chief
Response and Remediation Branch — Date

FIGURES
Compliance Evaluation Inspection Report
Boston Scientific (Guidant)
Dorado, Puerto Rico
EPA ID: **PRD987370723**

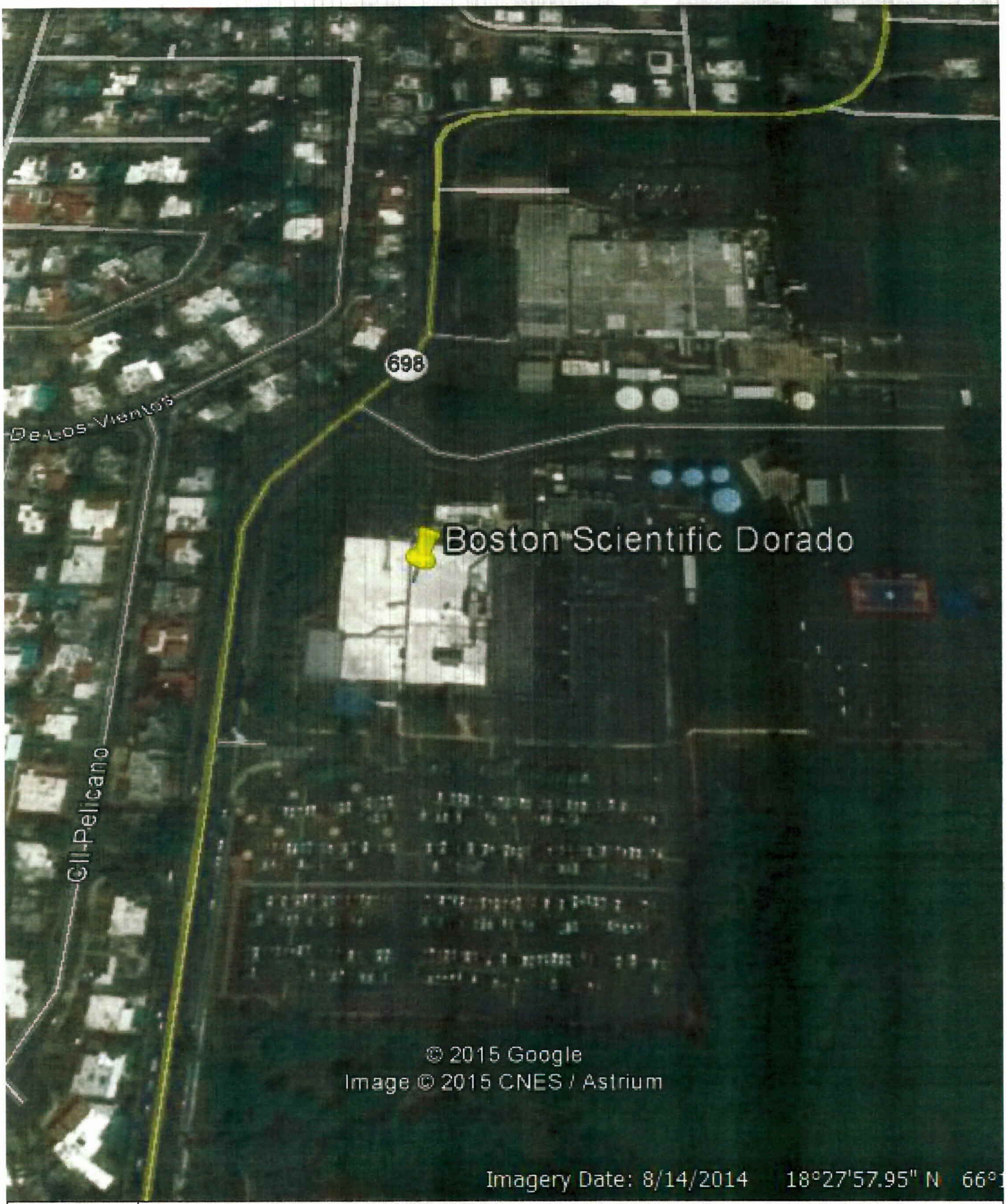


Title:

Figure 1: Boston Scientific (Guidant), Dorado, Puerto Rico

EPA ID: PRD987370723

Project: CEPD-RCRA-12-0225



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY	Title: Figure 2: Boston Scientific (Guidant), Dorado Aerial Photo
EPA ID: PRD987370723	Project: CEPD-RCRA-12-0225